

# BEST AVAILABLE COPY

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From-PATTON BOGGS

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T-168 P.04 F-172

Application No.: 10/617159

Docket No.: 023435.0101PTUS

## AMENDMENTS TO THE SPECIFICATION

Please delete the "References Cited [Reference By]" and "Reference List" sections beginning on the first paragraph of page 2 and continuing through the middle of page 6. These references will be submitted with a separate and properly filed information disclosure statement.

Please replace the first paragraph on page 19 with the following paragraph:

The QT and QTc intervals may be individually placed in the bins according to their measurement as described in Shell and Callahan. In a preferred embodiment the composite curves are constructed by software programs that generate a time series of approximately 100,000 data points long of RR/QT/ QTc triplets for each patient. Then the QTc data for each patient is binned in a histogram for that patient, finally, software is used to merge many patients' data into a composite data set (a "population") and to take means and standard deviations of this population (assuming normalcy of the data). Finally, more the data thus aggregated into two or more populations can then be compared, again using a combination of software and procedures as described in Press et al<sup>(1)</sup>, against each other to check for statistical difference between these two or more populations.

Please delete the last paragraph on page 9 titled, "Description of the Illustrations" and add the following paragraph before the paragraph titled, "DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT" on page 12 of the specification:

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Frequency of QT and QTc intervals in a Normal Subject

Figure 2. Frequency of QT and QTc intervals in a Patient with ILQT

Figure 3. QTc Interval Histogram of a Subject taking Cisapride

Figure 4. Holter Data Comparisons of composite curves from normal subjects, subjects on cisapride and subjects with Inherited Long QT Syndrome (ILQT)

Figure 5. Comparisons Pre/Post Dose of Drug using composite curves (N=19).

Figure 6. Individual Patient with ILQT Compared to a Composite Histogram of Normal Subjects